

Paul E. Harris and Charles Hesdorffer  
Serial No.: 09/726,883  
Filed: November 30, 2000  
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**REMARKS**

Claims 1-5 and 8-13 were pending. Claims 6 and 7 were previously canceled, without prejudice or disclaimer. By this Amendment, Applicants have canceled claim 12, without prejudice or disclaimer, and amended claims 1, 2, 5, 8 and 13 to place the claims in better form for examination. Applicants maintain that no new matter and no new issues are presented by this amendment, and request that this Amendment be entered. Accordingly, claims 1-5, 8-11 and 13 are now pending and presented for examination in connection with the subject application, with claims 1, 2 and 13 being in independent form.

**Rejection under 35 U.S.C. §112, first paragraph**

In section 4 of the January 28, 2004 Office Action, claims 1-5 and 8-13 were rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The Examiner stated that Applicant has not added any new arguments in support of the invention of the instant claims. The Examiner further stated that the rejection is maintained for the reasons of record which are reiterated here.

The Examiner stated that step (a) recites the loading of "blood mononuclear cells" into a cell culture container. The Examiner further stated that the specification, however, discloses that it is a "requirement" that the method of the instant claims begin with monocytes and monocyte precursors separated from lymphocytes. The Examiner also stated that the method of the instant claims would be highly unpredictable given that the

recitation of "blood mononuclear cells" would include lymphocytes in the starting material.

The Examiner stated that regarding step (c) in claim 1 and step (d) in claim 2, and the recitation of "separating nonadherent cells and cells adhered to the beads", claims 1 and 2 fail to indicate which group of cells is used to generate dendritic cells. The Examiner further stated that the method of the claims must again be considered highly unpredictable because it would appear that the method intends the further culture of one group of cells and the discarding of the other group, but the claims fail to indicate which group is saved and which group is discarded.

The Examiner stated that regarding the incubation of the blood mononuclear cells of the instant claims, the generation of dendritic cells from said blood mononuclear cells would require the inclusion of specific reagents in the incubation, at minimum GM-CSF (in all dendritic cell cultures) and TGF- $\beta$  (in human dendritic cell cultures, note the intended use of the DCs for the treatment of cancer patients which would encompass human use).

The Examiner stated that regarding the method of claim 12, wherein a ratio has a value sufficient to hold enough media for incubation, the specification fails to disclose what values would be considered sufficient. The Examiner further stated that as recited, the value would encompass a surface area ranging from that of the container alone (no microcarrier beads), to a container packed full of microcarrier beads. The Examiner also stated that it is unclear, however, if either of said values would allow for the reproducible generation of dendritic cells. The Examiner stated that the method of the instant claim must be

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considered highly unpredictable and requiring of undue experimentation.

By this Amendment, claim 12 has been canceled, without prejudice or disclaimer, and claims 1 and 2 have been amended to place the claims in better form for examination, with particular attention to the points raised by the Examiner. Applicants respectfully submit that the claimed invention described in the amended claims is fully enabled by the specification.

Accordingly, Applicants respectfully requests that the Examiner reconsider and withdraw the rejection under 35 U.S.C. §112, first paragraph.

**Rejection under 35 U.S.C. §112, second paragraph**

In section 7 of the January 28, 2004 Office Action, claim 8 was rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, specifically, the claim depends on canceled claim 7.

By this Amendment, claim 8 has been amended to depend from claim 1.

Accordingly, Applicants respectfully requests that the Examiner reconsider and withdraw the rejection of claim 8 under 35 U.S.C. §112, second paragraph.

**Rejection under 35 U.S.C. §112, first paragraph**

In section 8 of the January 28, 2004 Office Action, claim 13 was rejected under 35 U.S.C. §112, first paragraph, as allegedly as

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the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. The Examiner stated that this is a new matter rejection.

The Examiner stated that the specification and the claims as originally filed do not provide support for the invention as now claimed, specifically: (a) "preparing the unprocessed content of the cell culture container," (step b), (b) further recitations of "unprocessed contents", and (c) "harvesting the dendritic cell culture from the incubated contents of the cell culture container, including agitating said incubated contents, allowing the beads in the cell culture container to settle after said agitating, and expressing off cell culture suspension into another container," (step e).

The Examiner stated that Applicant indicates that no new matter has been added but fails to indicate where support for the new limitations can be found in the specification.

By this Amendment, claim 13 has been amended to place it in better form for examination, with particular attention to the points raised by the Examiner. Applicants respectfully submit the claimed invention as recited in the amended claims is fully enabled by the specification and the specification reasonably conveys to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Accordingly, Applicants respectfully request that the Examiner

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reconsider and withdraw the rejection of claim 13 under 35 U.S.C.  
§112, first paragraph.

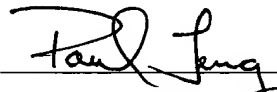
In view of the amendments to the claims and remarks hereinabove,  
Applicants maintain that claims 1-5, 8-11 and 13 are now in  
condition for allowance. Accordingly, Applicants earnestly  
solicit the allowance of the application.

If a telephone interview would be of assistance in advancing  
prosecution of the subject application, Applicants' undersigned  
attorneys invite the Examiner to telephone them at the telephone  
number provided below.

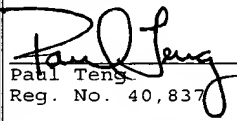
If a petition for an extension of time is required to make this  
response timely, this paper should be considered to be such a  
petition, and the Commissioner is authorized to charge the  
requisite fees to our Deposit Account No. 03-3125.

No fee is deemed necessary in connection with the filing of this  
Amendment. However, if any fees are required, authorization is  
hereby given to charge the amount of any such fee to Deposit  
Account No. 03-3125.

Respectfully submitted,



John P. White, Reg. No. 28,678  
Paul Teng, Reg. No. 40,837  
Attorneys for Applicants  
Cooper & Dunham LLP  
1185 Avenue of the Americas  
New York, New York 10036  
(212) 278-0400

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.	
 Paul Teng Reg. No. 40,837	April 8, 2004 Date